

## REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-4, 6-12, 14-19 and 21-29 are pending.

The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. As amended, claims 14 and 21-22 depend from pending claims. Entry of the amendments is requested to address the Examiner's objections on page 4 of the Office Action. They could not be earlier presented because the objections were initially raised in the final Office Action.

### *35 U.S.C. 102 – Novelty*

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1-3, 7 and 21-22 were rejected under Section 102(b) as allegedly anticipated by Gallatin et al. (U.S. Patent 5,728,533). Applicants traverse.

It was alleged in the Office Action that Gallatin disclose cellular expression of a first construct comprising a reporter gene driven by a promoter and a second DNA sequence from a library, wherein expression of the reporter gene is detected. Without any admission regarding this allegation, independent claim 1 is amended to require a method comprising (emphasis added):

- (a) co-transfecting a cell with (i) a first vector selected from a library of vectors, at least two members of said library comprising genes which encode different test proteins, and (ii) a second vector comprising a gene which encodes a reporter protein, wherein said reporter protein affects or regulates a biological process in said cell;
- (b) expressing said different test proteins and said reporter protein in a transfected cell;
- (c) measuring abundance and/or activity of said reporter protein by observation of an indicator of said biological process in said transfected cell, wherein said abundance

and/or activity of said reporter protein is modulated by the presence of a protein that modulates said reporter protein; and

(d) screening said library for one or more members which encode test proteins that modulate said reporter protein.

In order to anticipate the claims, a reference must teach each and every element of the claimed invention. Gallatin does not anticipate the claims because the cited document does not teach screening a library of vectors for a member that has a desired activity, nor does it teach the use of a reporter protein that affects or regulates a biological process in a cell. In the final Office Action, the Examiner refers to his previous Office Action where both of these limitations were alleged to be taught by Gallatin. This apparently refers to the citation in the Office Action mailed April 18, 2008 of column 5, second full paragraph (emphasis added):

A modified version of the foregoing assay may be used in isolating a polynucleotide encoding a protein that binds to  $\alpha_d$  by transforming or transfecting appropriate host cells with a DNA construct comprising a reporter gene under the control of a promoter regulated by a transcription factor having a DNA-binding domain and an activating domain, expressing in the host cells a first hybrid DNA sequence encoding a first fusion of part or all of  $\alpha_d$  and either the DNA binding domain or the activating domain of the transcription factor, expressing in the host cells a library of second hybrid DNA sequences encoding second fusions of part or all of putative  $\alpha_d$  binding proteins and the DNA binding domain or activating domain of the transcription factor which is not incorporated in the first fusion, detecting binding of an  $\alpha_d$  binding protein to  $\alpha_d$  in a particular host cell by detecting the production of reporter gene product in the host cell, and isolating second hybrid DNA sequences encoding  $\alpha_d$  binding protein from the particular host cell.

Underlining emphasizes the two limitations/elements being compared. Comparing Applicants' claimed method to Gallatin's disclosure, the various differences therebetween are clearly evident, particularly with respect to the transfection and expression steps. First, Gallatin describes transfecting host cells with a single DNA construct whereas claim 1 transfection requires co-transfecting a cell with (a) a first vector selected from a library of vectors and (b) a second vector comprising a gene coding for a reporter protein. Just as Gallatin's transfection step differs from the transfection in Applicants' claim 1, their expression step(s) also differ. Applicants' claim 1 requires expression of different test

proteins and the reporter protein in a transfected cell whereas Gallatin's two expression steps call for expressing a first hybrid DNA sequence encoding a first fusion protein, followed by expressing a library of second hybrid molecules encoding a second fusion. For at least these reasons, Gallatin does not anticipate the instant claims.

Moreover, those claims depending from the independent claim are also not anticipated by the cited document because the limitations of claim 1 are incorporated in claims depending therefrom. See *In re McCarn*, 101 USPQ 411, 413 (C.C.P.A. 1954).

Applicants submit that these features of their claimed invention are sufficient to distinguish over the cited document so any other incorrect allegations about its disclosure are not disputed here, but the opportunity to dispute them in the future is reserved.

Withdrawal of the Section 102 rejection is requested because the cited document fails to disclose all limitations of the claimed invention.

### *35 U.S.C. 103 – Nonobviousness*

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *In re Kahn*, 78 USPQ2d 1329, 1334 (Fed. Cir. 2006) citing *Graham v. John Deere*, 148 USPQ 459 (1966). The *Graham* analysis needs to be made explicitly. *KSR v. Teleflex*, 82 USPQ2d 1385, 1396 (2007). It requires findings of fact and a rational basis for combining the prior art disclosures to produce the claimed invention. See *id.* (“Often, it will be necessary for a court to look to interrelated teachings of multiple patents . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue”). The use of hindsight reasoning is impermissible. See *id.* at 1397 (“A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning”). Thus, a prima facie case of obviousness requires “some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct.” *Kahn* at 1335; see *KSR* at 1396. A claim directed to a combination of prior art elements “is not proved obvious merely by demon-

strating that each of its elements was, independently, known in the prior art.” Id. A determination of prima facie obviousness requires a reasonable expectation of success. See *In re Rinehart*, 189 USPQ 143, 148 (C.C.P.A. 1976).

Claims 1, 3-4, 6, 8-12, 14-19 and 23-24 were rejected under Section 103(a) as allegedly unpatentable over Gallatin et al. (U.S. Patent 5,728,533) in view of Hillman et al. (U.S. Patent 5,942,399). Applicants traverse.

Gallatin was discussed above. It was further alleged in the Office Action that Hillman discloses the additional elements recited in the dependent claims. Hillman does not address the deficiencies described above with respect to Gallatin’s disclosure. Thus, the combination of Gallatin and Hillman does not render obvious the claimed invention.

Further, one of ordinary skill in the art would not have found it obvious from the cited documents (neither individually nor in combination) to co-transfect a cell with a first vector selected from a library of vectors, at least two members of said library comprising genes which encode different test proteins, and a second vector comprising a gene which encodes a reporter protein, wherein that reporter protein affects or regulates a biological process in said cell. Moreover, there is nothing in the record to render obvious modifying the two documents, either individually or in combination, to make the present claimed invention with a reasonable expectation of success.

Applicants submit that these features of their claimed invention (e.g., different transcription and expression steps) are sufficient to distinguish over Gallatin and Hillman so any other incorrect allegations about their disclosures are not disputed here, but the opportunity to dispute them in the future is reserved.

Withdrawal of the Section 103 rejection is requested because the claims would not have been obvious to one of ordinary skill in the art when this invention was made.

### *35 U.S.C. 112 – Definiteness*

Claims 4-5, 14 and 21-22 were rejected under Section 112, second paragraph, as allegedly “indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” Applicants traverse.

Tradenames in claim 4 are deleted as suggested by the Examiner. Claim 5 was canceled without prejudice or disclaimer on October 20, 2008.

Claims 14 and 21-22 are amended to depend from pending claims.

Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

*Conclusion*

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if additional information is required.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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